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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/539,585 | 06/17/2005 | Yusei Miyamoto | | 4514 |

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| EXAMINER | |
|---|---|
| PAK, JOHN D | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/539,585 | MIYAMOTO ET AL. | |
| | Examiner | Art Unit | |
| | JOHN PAK | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 12-22 is/are pending in the application.

4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 12-15 and 19-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 6/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 12-22 are pending in this application.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

> Group I, claims 12-15 and 19-22, drawn to nanocolloidal platinum dispersion or drink, comprising nanocolloidal platinum and a polyacrylic acid salt, the nanocolloidal platinum having an average particle size of 1-5 nm, 90% or more of said nanocolloidal platinum having a particle size in the range of 0.1-10 nm.
>
> Group II, claims 16-18, drawn to method for producing nanocolloidal platinum dispersion. This method does not require any size requirement for the nanocolloidal platinum.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

Under lack of unity rules, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The "contribution over the prior art" is considered with respect to novelty and inventive step. See PCT Rule 13.1 and 13.2; see also MPEP 1850.

Here, the only potential corresponding "special technical feature" between the two invention groups is a nanocolloidal platinum dispersion with a polyacrylic acid salt. However, applicant's specification paragraph 14 admits that sodium polyacrylate is a known protecting agents of metal colloids and Devi et al. (Bull. Mater. Sci., Vol. 23(6), 2000, pp. 467-470) disclose nanosized platinum colloids in sodium salt of polyacrylic acid (see in particular paragraph bridging pages 469-470).

Therefore, there is no special technical feature that defines a contribution which each of the inventions makes over the prior art. The claims thereby lack a unity of invention.

During a telephone conversation with Mr. Olexy on 9/11/2007 a provisional election was made without traverse to prosecute the invention of Group I, claims 12-15 and 19-22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 16-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) Claim 14 depends on claim 12. Claim 14 recites "said colloid-protecting agent" but claim 12 does not provide antecedent basis for "colloid-protecting agent."

(2) The molar ratio in claim 14 is unclear. It is unclear whether the relative molar quantity of the colloid-protecting agent is based on the actual molar quantity of the polymer (e.g. polyacrylate) or the monomer of the polymer.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-15 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2002-212102 in view of JP 11-346715 (abstract), El-Sayed (US 6,090,858), HCAPLUS abstract 2001:47787, and applicant's acknowledged prior art.

JP 2002-212102 discloses orally ingestible colloidal platinum particles having a size of 2-3 nm, dispersed in a state to form aggregates having a size of 4-8 nm (see

abstract cited by applicant). The particles are processed by surfactants (claim 3, see enclosed Machine translation).

English abstract of JP 11-346715 discloses a 0.0001-0.1% colloidal solution of two platinum group metals, including platinum (see enclosed Patent Abstracts of Japan). Elimination of active oxygen is disclosed (id.).

El-Sayed discloses a method by which nanoparticles of desired shape and size distribution can be produced (Figure 1). Degree of polymerization and concentration of the stabilizing polymer used to produce colloidal particles influence size distribution and stability – for example, higher ratio of the stabilizing polymer (capping material) to metal produces smaller gold particles (column 1, lines 46-53). Platinum nanoparticles are disclosed (e.g. column 3, lines 32-33). Varying the amount of the polyacrylate stabilizing polymer to provide repeatable controlled production of platinum nanoparticles is disclosed (see from column 3, line 32 to column 5, line 25).

HCAPLUS abstract 2001:47787 similarly discloses stable dispersions of platinum nanoparticles, wherein the size of nanoparticles is controlled by changing the ratio of concentration of the capping polymer (stabilizing polymer) to the concentration of the platinum cation used.

Applicant acknowledges in the specification that sodium polyacrylate, a known, safe food additive, is known to be used as a protecting agents of metal colloids (paragraph 14).

JP 2002-212102 does not disclose a nanocolloidal platinum dispersion that contains a polyacrylic acid salt. Sizes of 2-3 nm particles and 4-8 nm aggregates (disclosed by JP 2002-212102) meet applicant's size features. One having ordinary skill in the art would have had sufficient motivation to add a polyacrylate such as sodium polyacrylate to the nanocolloidal platinum dispersion of JP 2002-212102. As established by El-Sayed and applicant's acknowledged prior art, sodium polyacrylate would have been expected to stabilize the nanocolloidal dispersion and help control the production process.

The specific molar ratio (R value, assumed for the purpose of this discussion to be based on monomer) of 80-180 to 1 (polyacrylate to platinum) of applicant's claim 13 is not expressly disclosed by JP 2002-212102 or any of the secondary references, mainly because this is not how the cited prior art expresses the ratio between the capping material and the metal. El-Sayed provides several specific examples and discloses 1:1, 5:1 and 2.5:1 molar ratios (polyacrylate polymer molar amount to platinum molar amount). As El-Sayed teaches the degree of polymerization and concentration of the stabilizing polymer used to produce colloidal particles to influence size distribution and stability, one having ordinary skill in the art would have been able to arrive at the claimed R value by routine experimentation with known polyacrylate stabilizing polymers of varying degrees of polymerization.

Applicant's claim 13, which requires $IC_{50}$ of 200 µmol/L or less, is not expressly disclosed by any of the cited references. However, the cited abstract of JP 11-346715 establishes that platinum group colloidal dispersions, at 0.0001-0.1% concentration, are effective in eliminating active oxygen. Given the fact that concentration of any agent for reducing active oxygen species by half depends on what the active oxygen species is and how much of it is to be reduced (what is half, half of something very dilute or half of something very strongly concentrated?), applicant's claim 13 is sufficiently broad enough to be suggested by teachings of the cited abstract of JP 11-346715. One having ordinary skill in the art would have expected the platinum nanocolloidal dispersion + polyacrylate suggested by the combined teachings of the cited prior art to have such an activity that a concentration of 200 µmol/L or less of the nanocolloidal platinum would be expected to reduce the concentration of some concentration of some active oxygen species to half.

Applicant's claim 20 recites 0.001-100 µmol/l nanocolloidal platinum. This is equivalent to about 0.0000000195 wt% to 0.00195 wt% nanocolloidal platinum. The abstract of JP 11-346715 discloses 0.0001 to 0.1% colloidal solution of two platinum group metals, including platinum. One having ordinary skill in the art would thus have found it obvious to formulate the nanoparticles of JP 2002-212102 at concentrations that are within applicant's claimed concentrations.

Applicant's claim 21 recites inclusion of cations and an osmotic pressure of 250-350 mOsm/kg. Sodium ion is already included by the obvious incorporation of sodium polyacrylate. Addition of other cations such as potassium, magnesium and calcium would have been obvious for a drink with health benefits (JP 2002-212102 & JP 11-346715 (abstract)). Osmotic pressure of 250-350 mOsm/kg would have been obvious since the osmolality of normal body fluid is within that range.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Claims 12-15 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2002-212102 in view of JP 11-346715 (abstract), El-Sayed (US 6,090,858), HCAPLUS abstract 2001:47787, and applicant's acknowledged prior art, further in view of Zinke (US 3,878,664).

This ground of rejection is essentially the same as the one set forth above and the full rationale set forth above incorporated herein by reference. The only addition to the incorporated rationale is that Zinke is cited to clearly establish for the record that normal human blood plasma has an osmolality of 298 mOsm per liter (kg) at 37°C. Delivering a drink that has an osmolality which is within the osmolality (i.e. osmotic

pressure) of physiological fluids would have been obvious from the motivation to minimize adverse physiological impact.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

It is noted for the record that copending claims in 10/546,058 (published as 2007/0141173) have been reviewed. No further action is deemed to be necessary at this time.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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